

REMARKS

Claims 7-24 are pending in the present application. The following rejection is at issue: Claims 7-24 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cain et al. (WO 97/18320). Applicants will submit a terminal disclaimer to obviate the double patenting rejections upon removal of the obviousness rejection. Applicants thank the Examiner for removal of the enablement rejection.

A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue.¹ In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent there from.² Applicants respectfully Cain does not teach each element of the invention as claimed.

As previously argued and addressed in detail below, the Declaration of Mr. Asgeir Sæbo establishes that the product obtained by Cain necessarily contained greater than 1% of the 8,10 and 11,13 isomers of CLA (octadecadienoic acid). The Examiner's interpretation of the data presented in the Declaration and the surrounding legal issues appear to be misguided.

1. The Skilled Person Recognizes that the Cain CLA Compositions Necessarily Contain the 8,10 and 11,13 Isomers

In paragraph 5 of the Office Action, the Examiner admits that's "Cain et al. do not specifically discuss peak area percentages of 11,13-octadecadienoic and 8,10-octadecadienoic acid . . ." The Examiner then goes on to state that the claimed compositions would be obvious because the compositions that are disclosed contain only the c9,t11 and t10,c12 isomers because the stated percentages of those isomers adds up to 100 percent. **Applicants respectfully submit that the Examiner is citing Cain for a claim limitation as to which Cain is silent.** As established in the Sæbo Declaration, a person of skill in the art knows that other isomers besides the t10,c12 and c9,t11 isomers are necessarily produced when linoleic acid is isomerized by the

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

² §MPEP 2143.03.

method used by Cain. (See paragraph 5 of the Sæbo Declaration). Thus, upon reading the Cain reference, the skilled person in the art would realize that the relative percentages of the t10,c12 and c9,t11 isomers were being reported only as to each other and not other CLA isomers such as the 8,10 and 11,13 isomers. In other words, the only logical conclusion that a person of skill in the art could reach is that the data was reported by adding only the amounts of t10,c12 and c9,t11 isomers present in the composition and then dividing the amount of t10,c12 or c9,t11 by that total amount. The amounts of the other isomers that were necessarily present were not included in the calculations. **As discussed in more detail below, the Examiner has not provided evidence or reasoning as to why one skill in the art would either a) not believe the objective evidence contained in the Sæbo Declaration or 2) believe that the process used by Cain would not also produce the 8,10 and 11,13 isomers of CLA.** Indeed, the Examiner's admission in paragraph 9 of the Office Action that linoleic acid is subject to sigmatropic rearrangement confirms the fact that the 8,10 and 11,13 isomers had to be present in the Cain CLA compositions. Instead of rebutting the evidence offered by the Applicants, the

2. The Examiner Has Provided No Objective Evidence of Record to Rebut the Applicants Factual Evidence

Instead of rebutting the objective, factual evidence offered by the Applicants or explaining why one of skill in the art would not believe that the Cain methods necessarily produced the 8,10 and 11,13 isomers, the Examiner has relied on case law which is both factually and legally distinguishable from the present application. It is clear that the Examiner has used this misguided approach because he cannot rebut the Applicants objective data and explanations of why the Cain methods necessarily produced the 8,10 and 11,13 isomers of CLA.

In paragraph 5 of the Office Action, the Examiner says that the data offered by Applicants lacks "probative force" and cites *In re Michalek* for the proposition "that it is not a difficult matter to carry out a process in such a fashion that it would not be successful and, therefore, the failure of experimenters who have no interest in succeeding should not be accorded great weight." 74 USPQ 108, at 109.

Applicants respectfully submit that the Office's "well-settled" case law is not settled at all, and, in fact, is not in accordance with proper PTO practice. The decision relied on by the Examiner is more than 50 years old. While this case has not been directly overruled, it is in conflict with current case law and PTO practice. In particular, the Examiner 's failure to accord the proper weight to the Sæbo Declarations does not conform with proper patent practice

according the Manual of Patent Examining Procedure (MPEP). The Office must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.³

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.⁴

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, **whether buttressed by experiment, prior art references, or argument**, the entire merits of the matter are to be reweighed. (Emphasis added)⁵

Accordingly, even if the Examiner had established a *prima facie* case of obviousness (and

³ MPEP §§2144.08; emphasis added.

⁴ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

⁵ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

Applicants contend that the Examiner did not), the Examiner must respond to the information presented in the Declaration. The above directions of the court and the PTO state that the evidence **must be considered**. These directions do not categorize evidence according to whether it is developed by interested or disinterested parties and do not state that evidence developed by the inventor **may be ignored**. **The directions specifically state that experimental evidence, such as that contained in the Declaration, must be considered**. Indeed, the Office must start over and reconsider the entire obviousness analysis.

Any distinction between giving evidence “no weight” or “great weight,” based upon the teaching of *In re Michalek*, does not relieve an Examiner from addressing the cited holdings. Indeed, the Office must address the cited holdings of *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976) and *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). In particular, per *In re Hedges* and *In re Rinehart*, the Examiner must **respond** to the information presented in the Declarations in a manner indicating that the evidence was considered. The Examiner’s conclusory statements do not indicate that evidence provided in the Declarations was properly considered and evaluated.

Indeed, in the present case, there was no reweighing of the merits by the Examiner. Instead of actually analyzing the Declarations and the factual, experimental data contained within them, the Examiner has summarily dismissed the data with no analysis because it was generated by the Applicants. Applicants submit that the results would be the same no matter who conducts the experiments. **The Examiner has failed to substantively address the data in the Declarations and offer any analysis of why the data is flawed.** As explained in detail below, *In re Michalek* is both legally and factually distinguishable.

1. *In re Michalek* is Legally Distinguishable

In re Michalek involved claims to a thermoplastic resin comprising polymers or copolymers of one or more nuclear-substituted dichlorostyrenes. *In re Michalek*, 34 C.C.P.A. 1124; 162 F.2d 229; 74 U.S.P.Q. 107 (1947). The court stated the following with respect to the affidavits submitted in support of patentability:

Several affidavits to sustain appellant's contention were filed. In substance it is stated therein that the processes of the Dreisbach patents do not produce monomeric dichlorostyrene sufficiently pure to meet the density and index of refraction recited in the claims or to polymerize, although it is not said that the processes of the patents are

incapable of producing the nuclear-substituted dichlorostyrenes mentioned therein. The board considered the affidavits insufficient to overcome the definite naming in those patents of dichlorostyrene and the indication that it is polymerizable. In this connection the solicitor in his brief cites *In re Von Bramer*, 29 C.C.P.A. 1018, 127 F.2d 149, 53 U.S.P.Q. 345.

With respect to the experiments described in the affidavits it must be said that in a patent it is to be presumed that a process, if used by one skilled in the art, will produce the product alleged by the patentee and such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. Skilled workers would as a matter of course, in our opinion, if they do not immediately obtain desired results, make certain experiments and adaptations and we agree with the argument of the solicitor that it is not a difficult matter to carry out a process in such fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight, citing *Bullard Company et al. v. Coe*, 79 U.S. App. D.C. 369, 147 F.2d 568, 64 U.S.P.Q. 359. Possibly more extensive experiments than were made by the affiants herein might have produced a different result.

It is clear from this discussion that the holding of the court was specific to the facts presented to it, and especially to the nature of the data contained in the affidavits. The court emphasizes this by stating "more extensive experiments" might have "produced a different result." Thus, *In re Michalek* **does not stand** for the proposition that all reproductions of prior art data by an inventor should be ignored simply because the inventor has no reason to be successful. Instead, the court in *In re Michalek* evaluated the data and found it insufficient. The Examiner has failed to do this in the instant case. As indicated above, the Examiner has provided no reasoning as to why the data submitted is insufficient or incorrect.

2. *In re Michalek* Is Factually Distinguishable

In re Michalek is also factually distinguishable. The Examiner has attempted to ignore the evidence provided by Applicants by relying on *In re Michalek* and characterizing the evidence as a failure. To the contrary, the evidence presented by the Applicants is not a failure to repeat the results of Cain et al. as Cain et al. is **silent** as to the presence of the 8,10 and 11,13 isomers. The only way the Applicants results could be considered to be a failure is if Cain et al. affirmatively stated that the isomers were not present and then Applicants failed not to produce the isomers. This is not the present situation. Applicant's results supplement the teachings of

Cain et al. and do not contradict them.

The Examiner is misinterpreting and misapplying *In re Michalek*. First, the Declarations noted in *In re Michalek* was deemed insufficient because it failed to completely address the claimed material. Here, the Declarations provided by the Applicants establish that the methods used by Cain et al. and Cook et al. **could not** produce compositions comprising *less than 1%* trans,trans 8,10 and 11,13 octadecadienoic acid isomers. In particular, the Applicants followed the exact instructions of Cain et al. and analyzed the product. The Applicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cook et al. and Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by both Cook et al. and Cain et al. **Cain et al.'s silence concerning the presence of the isomers cannot be equated with the absence of the isomers.**

3. Cain Does Not Enable Production of the Claimed Compositions

In paragraph 6 of the Office Action, the Examiner alleges that “all of the necessary and required parts (wheels) are clearly taught and exemplified in Cain et al.” The Examiner further states that Cain teachings that the c9,t11 and t10,c12 isomers are the most beneficial isomers provides the skilled artisan with “clear motivation to decrease production of undesired CLA isomers, thus producing compositions of the desired c9,t11- and t10,c12-isomers of CLA.” See paragraphs 6 and 7. The Saebo Declaration establishes that this cannot be true because the methods utilized by Cain are incapable of producing the claimed compositions. In particular, the Cain reference does not teach the refined, carefully controlled methods utilized to produce the claimed compositions that are taught in the present application. Thus, Cain does not teach (or even hint at) a solution to the problem of unwanted isomers in CLA compositions. Since Cain does not teach methods capable of producing the claimed compositions, Cain does not enable production of the claimed compositions. Thus, the claimed compositions cannot be obvious in view of Cain.

4. There is No Ambiguity in Applicant's Data

In paragraph 8 of the Office Action, the Examiner alleges that there is ambiguity with coelution of the t8,c10 and c9,t11 isomers. This alleged “ambiguity” is completely irrelevant to the data contained in the Saebo Declaration because the claims specify less than 1% of the 8,10

and 11,13 isomers. Because the Saebo Declaration demonstrates the presence of 3.49% of the 11,13 isomers, which on its own is much higher than claimed limitation of less than 1% 8,10 and 11,13 isomers, the amount of the 8,10 isomer present is irrelevant. Furthermore, the Examiner's attempt to create an ambiguity in the data is without scientific basis. The Applicants provided an explanation of how one of skill in the art analyzes CLA by current, scientifically established and validated methods. The Examiner provides no support (for example, by citing to a relevant scientific paper) for his supposition that coelution "could very well give different ratios of the isomers and thus fall within the instantly claimed ranges." This statement is completely unsubstantiated and without scientific support.

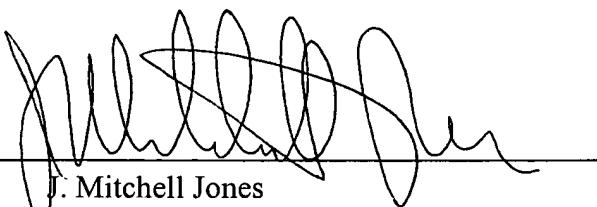
5. There is No Motivation to Modify

As explained above, the Cain et al. reference does not teach methods which can produce the claimed compositions. Furthermore, the Cain reference does not identify parameters which could be changed to produce the claimed compositions. Thus, there is no motivation to modify the Cain reference to achieve the claimed compositions. Applicants reincorporate their arguments from their previous response regarding hindsight reconstruction and preserve those arguments for appeal. Despite the Examiner's arguments, the fact remains that he cannot point to a prior art reference which teaches that the double bonds of CLA are a sigmatropic systems and that the reaction to obtain CLA could be controlled to the extent necessary to produce the claimed compositions. There is no expectation of success, and indeed, an invitation to experiment is not even present in the prior art. The recognition that the isomer compositions of CLA products could be controlled by the reaction conditions utilized by the inventors was not present or suggested anywhere in the prior art. Thus, the Examiner's conclusions regarding sigmatropic rearrangement could only be derived from the applications and the Saebo Declaration. Indeed, this line of reasoning did not even occur to the Examiner until it was brought to the Examiners attention by the Applicants in the Saebo Declaration and a 2002 article written by one of the inventors. If the fact CLA double bond systems could be recognized as sigmatropic was apparent prior to the filing date of the present application, then it is unlikely that sigmatropic rearrangement would have been the subject of a scientific publication 4 years after that filing date.

Conclusion

All grounds of rejection and objection of the Office Action of October 1, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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